

REMARKS

Claims 26, 27, 31-33, 36-39 and new claims 40-47 are pending.

The support for the claim amendments are as follows: Claims 26, 27, 32, 33, 39: (p.14-17); Claim 31: (p.43, last paragraph); Claim 36, 37, 38: (written in independent form); new Claim 40: (Claim 26); new Claim 41: (claim 27); new Claim 42: (claim 32); new Claim 43: (claim 33); new Claim 44: (claim 36); new Claim 45: (claim 37); new Claim 46: (claim 38); and new Claim 47: (claim 39). The applicant respectfully submits that no new matter has been added. It is believed that this Amendment is fully responsive to the Office Action dated October 24, 2006.

The specification has been objected to due to certain informalities, which the Examiner deemed needed correction, as set forth in item 4, page 2 of the outstanding Action. The specification has been amended. No new matter has been added.

Examiner notes that applicants have not updated the relationship of the instant application to its parent application that has matured in to a US patent. Examiner urges applicants to amend said information by providing the US patent number in response to this Office action. (Office Action, p. 2)

Applicant respectfully submits that the amendment to the specification obviates the objection to the specification. Accordingly, withdrawal of the objection to the specification is respectfully solicited.

Claims 36-38 are objected to because of the following informalities: Claims 36-38 fail to

recite biological names in italics. Appropriate correction is required. (Office Action, p. 2)

The names of microorganisms recited in claims 36-38 have been italicized as suggested by the Examiner.

Claims 26-30, and 39 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. (Office action, p. 3)

Claims 26-27 have been amended to replace "An enzyme" with "An isolated enzyme"; Claim 30 has been amended to replace "A polypeptide" with "An isolated polypeptide"; and Claim 39 has been amended to replace "an enzyme" with "an isolated enzyme", as suggested by the Examiner to overcome the rejection.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action, p. 3)

Claim 28 has been canceled making this rejection now moot.

Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action , p. 4)

Claim 31 has been amended to identify the degree of the homology as "80% or more". This amendment is supported by the specification as filed, page 43, the last paragraph. Please note that the same amendment was accepted for the parent application (Serial No. 09/727,769, Patent No. 6,756,221).

The Examiner asserts that claim 31 is indefinite. In response, the applicants have attached a Declaration (the signed Declaration will follow) to show specifically that claim 31 as amended is clear to the skilled artisan. Thus for the following reasons, the rejection should be withdrawn:

The nucleotide sequence of the deamidation enzyme of the present application, *Chryseobacterium gleum*, and that of related application No. 09/727,769, *Chryseobacterium* sp. No. 9670, have about 80% homology. This is compelling evidence that the percent homology is a good basis on which to predict function.

Furthermore, the hybridization method is to obtain DNA having nucleotide homology with the template DNA by utilizing the ability to form double strands. Because this method utilizes the sequence actually obtained (Seq. No. 5), one skilled in the art expects that sequences having a high homology can be obtained.

Either of these factors, homology or hybridization, which relies on homology, is the means for narrowing the sequences expected to encode active protein. Once identified, the homologous sequence is more likely to have the activity recited in the claims. A simple screening method, as outlined in the specification, can be used to confirm the activity.

Based on this showing and the Declaration, it is requested that the rejection be reconsidered and withdrawn.

Claims 32-33 and claims 34-38 depending there from are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office Action, p. 4)

Claims 32-33 have been amended to replace "a novel enzyme" with "an enzyme", as suggested by the Examiner to overcome the rejection.

Claims 26-29, 31-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide or a composition comprising SEQ ID NO:6 ... (Office Action, p. 5) See below.

Claims 26-29, 32-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Office Action, p. 8) See below.

Claims 26-29, 32-39 are rejected under this section of 35 USC 112 because the claims are directed to a genus of polypeptides derived from SEQ ID NO: 6 including modified polypeptide sequences, modified by at least one of deletion, addition, insertion and substitution of an amino acid residue in SEQ ID NO:6 and fragments of SEQ ID NO:6 that have not been disclosed in the specification as well as method of making said polypeptides using transformed cells. (Office Action, p. 8)

In response to the three rejections above:

Claims 26-27 have been amended to cover enzymes obtained from the organisms supported by the specification as filed (i.e. *Cytophagales* and *Actionomyce*). Claim 28 has been canceled. New claims 40-41 have been introduced which feature the microorganism *Flavobacteriaceae*.

Claim 29 has been canceled and claim 31 has been amended to replace the definition of modification with a definition using the degree of homology.

Claims 32-33 have been amended to cover enzymes obtained from the organisms supported by the specification as filed (i.e. *Cytophagales* and *Actionomyce*). Claims 34-35 have been canceled in favor of amended claims 32-33. New claims 42-43 have been introduced which feature the microorganism *Flavobacteriaceae*. Claims 36-38 have been rewritten in independent form. New claims 44-46 have been introduced in which the activity of the enzyme is defined in the same fashion as claim 27.

Claim 39 has been amended to only cover enzymes obtained from the organisms supported by the specification as filed (i.e. *Cytophagales* and *Actionomyce*). New claim 47 has been introduced which features the microorganism *Flavobacteriaceae*.

These claim amendments address all rejections over 35 USC 112, first and second paragraphs. It is respectfully requested that the rejections be withdrawn.

Claim 38 is rejected because the invention appears to employ a novel *Chryseobacterium* microorganism. (Office Action, p. 9)

The deposit has been made under the Budapest treaty as evidenced by the attached receipt of deposit document from the PCT branch, which was filed in the parent application, now USP 6,756,221. This should obviate the rejection.

Claims 26-27, 29-30, 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Vaintraub et al. (Office Action, p. 11)

As clearly explained in the specification on p.5, line 20 to p.6, line 18, Vaintraub cannot

legally anticipate the invention as now claimed:

There is a report suggesting existence of an enzyme originating from plant seed, which catalyzes deamidation of protein (cf. I.A. **Vaintraub**, L.V. Kotova, R. Shara, *FEBS Letter*, Vol. 302. 169-171 (1988)). Although this report observed ammonia release from protein using a partially purified enzyme sample, it is clear that this report does not prove existence of an enzyme of the present invention from [sic] the following reasons. **That is, since a partially purified enzyme sample was used, absence of protease activity was not confirmed, and no change in molecular weight of substrate protein after the reaction was not confirmed, there remains a possibility that not one enzyme but plural enzymes such as protease and peptidase acted on protein to release glutamine and/or asparagine as free amino acids and ammonia was released by glutaminase and/or asparaginase which deamidate these free amino acids or a possibility that glutamine-containing low molecular weight peptide produced in a similar way is deamidated by peptideglutaminase-like enzyme. In addition, there is a possibility that deamidation occurred as a side-reaction by protease.** In particular, it should be noted that this report clearly describes that a glutaminase activity which acted on free glutamine to release ammonia was present in the partially purified preparation used therein. (emphasis added)

In short, the enzyme preparation of Vaintraub et al. is obtained from plant seeds at the germination stage and thus cannot anticipate the microorganism product of the claimed invention. High amounts of protease and peptidase are expressed in seeds at the germination stage. Because the enzyme preparation of **Vaintraub** et al. is a **partially purified** product (refer

to Fig.1), there is a possibility that the deamidation activity observed by **Vaintraub et al.** is based on the **contaminated protease** alone or the contaminated protease with peptidoglutaminase and/or glutaminase.

Plant seeds generally contain reserve proteins that have a high amount of amido groups, such as gluten. Accordingly, one skilled in the art might consider the existence of a protein-deamidating enzyme in plant seeds based on the assumption that such enzyme would be required to assimilate the nitrogen derived from the amido groups. However, this is not the same for the microorganisms.

The enzyme preparation acts upon the amido group of free glutamine or of glutamine residue in protein (see p. 171, first paragraph). In contrast, the enzyme defined in the claims of the present application act upon the amido groups in protein or peptide, **but it does not act upon the amido group of free glutamine** (see the bottom three lines of p. 51, lines 20-26 of the specification).

Considering the showing above, the enzyme defined in the claims of the present application is definitely different from the enzyme preparation of Vaintraub et al. Accordingly, the invention of claims 26-27, 29-30, 32-33, 39 is not legally anticipated by Vaintraub et al. In light of this, it is respectfully requested that the rejection be withdrawn.

Claims 26-27, 29-30, 32-33, 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Vinogradov et al. (Office Action, p. 12)

The enzyme preparation of Vinogradov et al. is apparently a kind of glutaminase, because it acts upon the amido group of free glutamine or asparagine (see the abstract in English). To the contrary, the enzyme defined in the claims of the present application is a protein-

U.S. Patent Application Serial No. **10/815,774**
Response filed March 26, 2007
Reply to OA dated October 24, 2006

deamidating enzyme **characterized by that it act upon the amido groups in proteins or peptides, whereas it does not act upon the amido group in free glutamine.** Thus, the enzyme defined in the claims of the present application is definitely different from the enzyme preparation of Vinogradov et al. Accordingly, novelty of the inventions set forth in claims 26-27, 29-30, 32-33, 39 is not denied by Vinogradov et al.

It is respectfully requested that this rejection be withdrawn.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vaintraub et al. and Sambrook et al. (Office Action, p. 13)

As explained above, the enzyme preparation of Vaintraub et al. is definitely different from the enzyme of the present application. Thus, unobviousness of claim 31 is never be denied by a combination of Vaintraub et al. and Sambrook et al. It is respectfully requested that this rejection be reconsidered and withdrawn.

Claims 26-28, 30-31, 39 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 of prior U.S. Patent No. 6,251,651. (Office Action, p. 15)

Claims 28 and 30 are canceled making the rejection against them now moot.

U.S. patent No. 6,251,651 claims an isolated polypeptide (claims 1 and 2) and a recombinant polypeptide (claim 3). **The invention set forth in claim 39 of the present application is not an enzyme itself but a composition comprising an isolated enzyme.** Namely, the invention of

U.S. Patent Application Serial No. **10/815,774**
Response filed March 26, 2007
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claim 39 is not the same as those claimed in the prior USP 6,251,651.

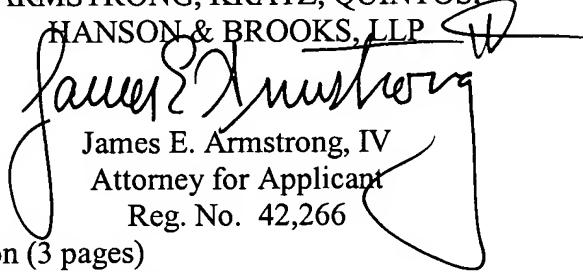
In view of the aforementioned amendments and accompanying remarks, claims 26, 27, 31-33, 36-39, as amended and new claims 40-47 are in condition for allowance, which action, at an early date, is requested.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicant's undersigned attorney at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicant respectfully petitions for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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Encls: Unexecuted Declaration (3 pages)
Chryseobacteriumu Deposit (2 pages)

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